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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,527	02/04/2002	Yukihiro Takada	FJN-058C1	8309

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,527	TAKADA ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed, September 9, 2004, is acknowledged. Claims 49, 53, and 54-55 were amended. Claims 49-60 are pending in this application.

2. All rejections made in the previous office action are hereby withdrawn. New grounds of rejection follow below in light of Applicants amendment to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 49-52 and 56-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Cioca et al. (US4285986) and Garantol-Gesellschaft, Ltd. (DE 178343) (abstract only).

The claims are drawn to a composition comprising degraded collagen, calcium and Vitamin D3.

The reference teaches a composition to be added to bulk animal food that comprises hydrolyzed collagen oligopeptides (see abstract and col. 3, lines 50-57). The reference states that the collagen oligopeptides can be combined with various micronutrients to be used in the feeding of suckling pigs. These include ascorbic acid, calcium phosphate, sodium chloride Vitamin A and Vitamin D3 (see col. 3, lines 25-31). Note that the disclosure of animal feed meet the limitation of oral administration to mammals of claim 1. The peptides obtained from collagen are obtained by hydrolyzing collagen with alkali earth metal

hydroxides to obtain oligopeptides that have a molecular weight between 5,000 to 20,000 (see col. 1, lines 50-66). This meets the limitation of claim 60. Further, the presence of calcium phosphate meets the limitation of claim 56 since egg shell calcium includes calcium phosphate (see DE 178343 abstract).

It is noted that one has to pick and choose vitamin D3 and calcium phosphate to come across Applicants claimed invention. The MPEP states "When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be 'at once envisaged.'"

Here, one of ordinary skill in the art can "at once envisage" the combination of oligopeptides from hydrolyzed collagen with calcium phosphate and vitamin D3 because the classes of ingredients are sufficiently limited or well delineated. Note that calcium phosphate and vitamin D3 are two compounds that can be chosen from a list of 21 different additives. The examples recite the combination of five to six different additives disclosed on the list. Thus one of ordinary skill in the art could "at once envisage" the combination of oligopeptides from hydrolyzed collagen with calcium phosphate and vitamin D3.

It is noted that claims 50-51 and 57-58 recite how the collagen is hydrolyzed, rendering the claims a product by process claim. The MPEP states "[E]ven though product-

by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Here the product is drawn to collagen. Chica et al. teaches that the major type of collagen is type I and is found in skin, bones and tendon (see col. 1, lines 23-26). Further the reference states that collagen can be obtained from variety of sources (see col. 2, lines 4-6). Here, the product obtain is hydrolyzed collagen product. Note that the degraded collagen claimed is also a hydrolyzed collagen. Both the products, disclosed in the patent and claimed, have the similar molecular weight. The claims state that the molecular weight is between 2-150 Kda and the prior art reference states that the molecular weight is between 5000 to 20000 daltons. Thus, the product is the same and the patentability of a product does not depend on its method of production or the source.

It is noted that in the response dated, 9-9-2004, that Applicants made arguments with regards to the use of a specific calcium product. Applicants stated that "Applicants specification teaches that a 'calcium agent with good absorptivety, such as calcium chloride, calcium carbonate, calcium lactate, egg shell or milk derived calcium etc." can be used according to the invention to enhance the strength of bone." Applicants argued forms such as "phosphates, oxalates, phylates and soaps' do not have good absorptivity. It is believed that such an argument would also apply to the current rejection, since the reference discloses the use of calcium phosphate. This argument has been addressed herein.

Claim 1 recites a composition for comprising degraded collagen, calcium, vitamin D3. The claims do not state that a particular type of calcium should be used or a specific

calcium salt should be used for a specific purpose. It is noted that "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." See MPEP 2111.01 citing Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). The reference discloses a composition for oral administration hydrolyzed collagen peptides, calcium, and vitamin D3. Thus, the reference meets all of the limitations of the claims and sufficiently anticipates the recited claims.

Finally, Applicants raised some issues, in their response, that the references applied did not teach that the composition was effective in inducing bone strengthening. It is assumed that Applicants would raise a similar argument for the instant rejection. However, In response to applicant's arguments, the recitation of bone strengthening has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 53-55 rejected under 35 U.S.C. 103(a) as being unpatentable over Cioca as applied to claims 49-52 above.

The claims are drawn to a composition comprising degraded collagen, calcium and Vitamin D3.

The reference of Cioca et al. has been discussed supra and the arguments raised above are herein incorporated. The difference between the prior art and the instant application is that the reference does not disclose teach the concentration of collagen and the ratio of collagen:calcium as claimed.

However, the MPEP states:

> "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")." See MPEP 2144.05.

Thus, it would have been obvious to optimze the cocentration of agents claimed in Cioco. The motivation would be to determine where in the disclosed general teaching is the optimal combination of the claimed ingredients.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

12/8/04

Anish Gupta
Patent Examiner